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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,987	09/09/2003	David E. Francischelli	P-10081.03	1294

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EXAMINER	
VRETTAKOS, PETER J	

ART UNIT	PAPER NUMBER
3739	

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08/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/657,987	FRANCISCHELLI ET AL.	
	Examiner	Art Unit	
	Peter J. Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *see attached*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1/16/07;12/08/03;5/20/04;2/13/06;11/3/06

DETAILED ACTION

Claims 1-20 are pending. The action is final.

The application is a divisional of 10/132,379 now USPN 6,648,883. Claims 1-14 are the analogous system claims to the patented method claims.

The filing date is 4-26-01 due to provisional application 60/287,202.

Note: intended use language (ex. method steps such as initiating energy responsive to measured impedance) does not add structure to a claimed invention in system claims. The rejections below reflect this maxim. In order to acquire patentable weight from intended use claim language, the Applicant should insert claim language positively reciting structure (related to the intended use) not found in the prior art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Nardella (5,713,896).

Independent claim 1

An ablation system (100, see figure 1), comprising:

generating means (106, 26) for generating ablation energy;

an ablation device (104, 10) comprising first ablation means (108) connectable to the generating means and locatable adjacent a first tissue site (102) to be ablated, for applying the generated ablation energy to the first tissue site;

a first impedance measuring electrode (112, col. 4:39-46) mounted to the ablation device (104) so that the first impedance measuring electrode (112) is adjacent the first tissue site (102) when the first ablating means (108) is adjacent the first tissue site;

impedance measurement circuitry (116, 26a) connectable to the first impedance measuring electrode to measure impedance at the first tissue site, using the first impedance measuring electrode (112, col. 4:39-46); and

control circuitry (118, 26a) operably coupled to the generating means to initiate and terminate the application of ablating energy to the first ablating means, wherein the control circuit is coupled to the impedance measurement circuit (see figure 3 where 26a and 26b rest adjacently) and terminates application of ablation energy to the first ablating means responsive to occurrence of an impedance plateau (implied by Nardella with the language, "power control means...for regulating the electrosurgical energy delivered to the living tissue...in response to the impedance signal *to maintain the tissue impedance within a preselected range*, " disclosed in column 10:39-45) measured

by the impedance measuring circuitry using the first impedance measuring electrode (112), following initiation of application of ablating energy to the first ablating means (see patented claim 1, especially the last limitation).

Dependent claims (parentheticals refer to Nardella)

2. A system as in claim 1 wherein the first ablating means (108) is a first ablation electrode (108) and wherein the generating means comprises an R-F generator (106, figure 1).

4. A system as in claim 2 wherein the first ablation electrode is employed (intended use language) as the first impedance measuring electrode. (108 is capable of being used as an impedance measuring electrode – it is the analogue of 112, which **is** employed as an impedance measuring electrode.) Also note the circuit in figure 2, which discloses analogous electrodes 146 and 148.

2. Claims 1-2 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Sherman (5,971,980).

Independent claim 1

An ablation system, comprising:

generating means (50) for generating ablation energy;

an ablation device (10) comprising first ablation means (22,26) connectable to the generating means and locatable adjacent a first tissue site to be ablated, for applying the generated ablation energy to the first tissue site (col. 7:5-16);

a first impedance measuring electrode (col. 7:5-16, related to 78) mounted to the ablation device so that the first impedance measuring electrode is adjacent the first tissue site when the first ablating means is adjacent the first tissue site;

impedance measurement circuitry (52) connectable to the first impedance measuring electrode to measure impedance at the first tissue site, using the first impedance measuring electrode; and

control circuitry (52) operably coupled to the generating means to initiate and terminate the application of ablating energy to the first ablating means, wherein the control circuit is coupled to the impedance measurement circuit (processor 52 performs both impedance measuring and feedback control as disclosed in col. 7:9-13) and terminates (intended use) application of ablation energy to the first ablating means responsive to occurrence of (intended use) an impedance plateau (it can be argued that a "plateau" is reached at the moment a measured limit reaches outside a predetermined range/threshold as disclosed in patented claim 1) measured by the impedance measuring circuitry (52) using the first impedance measuring electrode, following (intended use language) initiation of application of ablating energy to the first ablating means.

Dependent claims (parentheticals refer to Sherman)

2. Sherman discloses RF energy (col. 1: 55-58 and col. 3: 52) application via two ablating means / two RF electrodes (22 and 26).

4. A system as in claim 2 wherein the first ablation electrode is employed (intended use language) as the first impedance measuring electrode.

5,6. Sherman discloses monitoring by the processor (52) relative impedance changes (col. 7:5-23) (measured impedance over time) anticipating claims 5 and 6, which claim a processor (52). Detecting impedance plateaus and acceptable degree/rate of change is intended use language. These are merely steps in an ablation method. **There is no claimed structural difference** between the claimed processor and Sherman's processor (52).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nardella or Sherman.

As explained by the Applicant in the Response 2-9-06, claims 7-14 are duplication of parts from claims 1-6. The Office has established structural anticipation in Nardella and Sherman toward claims 1-6. MPEP 2144.04 VI.B. discloses duplication of parts in claims from parts in the prior art and the resulting obviousness. To this end, the claims are obvious in light of the prior art.

Claims 3 and 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman or Nardella in view of Chia et al. (5,913,856).

Sherman and Nardella neglect to disclose irrigated electrodes.

Chia et al. discloses, *inter alia*, an analogous RF ablation device that includes irrigated electrodes.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Sherman or Nardella in view of Chia et al. by including irrigated electrodes. The motivation would be to maintain a proper electrode temperature by a cooled fluid irrigation to partially compensate for the temperature rise due to RF energy delivery as posited in Chia et al. column 1 lines 62-67.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

The Applicant has pointed out the language from the specification required to make the deduction that the invention includes an "impedance measuring electrode". As such, all prior related 35 USC § 112 and 101 rejections are obviated. The Applicant has also explained how claimed functional language infers certain structural connections thereby obviating the remaining 35 USC § 112 rejections.

The Applicant is arguing that the prior art neglects to disclose circuitry that terminates the application of ablation energy responsive to the occurrence of an impedance plateau. There are several fallacies in this argument. First, the argument relies upon functional language to distance the claimed invention from the prior art. The Applicant has not shown the tangible physical structure found in the claimed invention that is not found in the prior art. Instead, the Applicant argues it has circuitry that does "X", while the prior art has circuitry that does "Y". How is the Office supposed to be credibly able to argue a structural difference between the two when there is no **tangible physical proof** of structural difference? And beyond arguing that the prior art circuitry and processor, and the claimed invention circuitry perform/function/operate differently what exactly is found (physical and tangible and **not** associated method steps) in the claimed invention/language that is not found in the prior art?

Second, what is the length of time required to establish a "plateau"? The Office argues that this is arbitrary and that a parameter such as impedance maintained at the slightest unit of time can be deemed a "plateau" of that parameter. As such, the prior

art's disclosure of feedback control of impedance is indeed disclosure of termination of energy application when impedance reaches a certain level for any period of time (establishing a plateau). In other words, because "plateau" is arbitrarily defined, one can argue that impedance at a unit value of 1 at for example 1 second (1000 consecutive milliseconds) has established a "plateau". The prior art discloses that outside of a predetermined range for impedance, energy application is controlled (for example, turned off) in response to the impedance value being outside of the predetermined range. Why is the impedance at that time, when it is not within a predetermined range, **not** considered to have reached a plateau? The Applicant is asked to apprise just what defines and how to define a "plateau"? Is there an objective period of time in which a parameter's value must reside in order to objectively state that a "plateau" has been reached?

The Examiner cannot and will not at this stage in prosecution make dispositive arguments toward claim language that rely upon the operation of black box structures ("circuitry", "processor") and arbitrarily defined words ("plateau").

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pete Vrettakos
July 31, 2007

Roy D. Gibson

ROY D. GIBSON
PRIMARY EXAMINER